



IFed 1653

Atty. Dkt. No. 058423-1218

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Himangshu S. BOSE, et al.

Title: METHODS AND
COMPOSITIONS FOR
REGULATION AND
MANIPULATION OF
STEROIDOGENESIS

Appl. No.: 10/510,593

International 20 May 2003

Filing Date:

371(c) Date: 19 September 2005

Examiner: Samuel W. Liu

Art Unit: 1653

Confirmation 9271
Number:

<p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.</p> <p><u>Deborah Beasley</u> (Printed Name)</p> <p><u><i>Deborah Beasley</i></u> (Signature)</p> <p><u>27 July 2006</u> (Date of Deposit)</p>

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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Commissioner for Patents
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Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-0872.

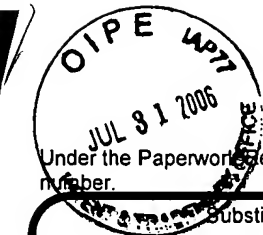
Respectfully submitted,

Date 27 July 2006

By 

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: July 27, 2006

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Sheet 1 of 3

Complete if Known

Application Number	10/510,593
Filing Date	20 May 2003
First Named Inventor	Himangshu S. Bose
Group Art Unit	1653
Examiner Name	Samuel W. Liu
Attorney Docket Number	058423-1218

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	P1	4,199,559		Ullman et al.	04-22-1980	
	P2	4,233,402		Maggio et al.	11-11-1980	
	P3	4,255,329		Ullman	03-10-1981	
	P4	4,318,707		Litman et al.	03-09-1982	
	P5	4,806,488		Berger, Jr. et al.	02-21-1989	
	P6	5,631,734		Stern et al.	05-20-1997	
	P7	5,856,102		Bierke-Nelson et al.	01-05-1999	
	P8	5,872,230		Stocco et al.	02-16-1999	
	P9	5,919,523		Sundberg et al.	07-06-1999	
	P10	5,989,833		Charon et al.	11-23-1999	
	P11	5,989,921		Charlton et al.	11-23-1999	
	P12	5,998,136		Kamb	12-07-1999	
	P13	5,998,163		Mierendorf et al.	12-07-1999	
	P14	6,194,555	B1	Stocco et al.	02-27-2001	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	D1	ARTEMENKO et al. "Mitochondrial Processing of Newly Synthesized Steroidogenic Acute Regulatory Protein (StAR), but Not Total StAR, Mediates Cholesterol Transfer to Cytochrome P450 Side Chain Cleavage Enzyme in Adrenal Cells" <i>J. Biol. Chem.</i> (2001) 276:46583-46596	
	D2	BAUER, M.F. and W. NEUPERT "Import of proteins into mitochondria: a novel pathomechanism for progressive neurodegeneration," <i>J. Inher. Metab. Dis.</i> (2001) 24:166-180	
	D3	BOSE, H.S. et al. "The Pathophysiology and Genetics of Congenital Lipoid Adrenal Hyperplasia" <i>N. Engl. J. Med.</i> (1996) 335:1870-1878	
	D4	BOSE, H.S. et al. "Incorrect Folding of Steroidogenic Acute Regulatory Protein (StAR) in Congenital Lipoid Adrenal Hyperplasia" <i>Biochemistry</i> (1998) 37:9768-9775	
	D5	BOSE, H.S. et al. "The Active Form of the Steroidogenic Acute Regulatory Protein, StAR, Appears to be a Molten Globule" <i>PNAS USA</i> (1999) 96:7250-7255	

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Examiner Name	Samuel W. Liu
Attorney Docket Number	058423-1218

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	D6	BOSE, H.S. et al. "N-218 MLN694, a Protein with StAR-like Steroidogenic Activity, Is Folded and Cleaved Similarly to StAR" <i>Biochemistry</i> (2000) 39 :11722-11731	
	D7	CHUCK, S. and V. LINGAPPA "Apolipoprotein B intermediates," <i>Nature</i> (1992) 356 :115-116	
	D8	CHUNG, B. et al. "Human Cholesterol Side-Chain Cleavage Enzyme, P450scc: cDNA Cloning, Assignment of the Gene to Chromosome 15, and Expression in the Placenta" <i>PNAS USA</i> (1986) 83 :8962-8966	
	D9	COLOMBINI et al. "The mitochondrial outer membrane channel, VDAC, is regulated by a synthetic polyanion," <i>Biochim. Biophys. Acta</i> (1987) 905 :279-286	
	D10	GORLICH et al. "A protein of the endoplasmic reticulum involved early in polypeptide translocation," <i>Nature</i> (1992) 357 :47-52	
	D11	GORLICH and RAPOPORT "Protein translocation into proteoliposomes reconstituted from purified components of the endoplasmic reticulum membrane," <i>Cell</i> (1993) 75 :615-630	
	D12	HANEIN et al. "Oligomeric rings of the Sec61p complex induced by ligands required for protein translocation," <i>Cell</i> (1996) 87 :721-732	
	D13	HARIKRISHNA, J.A. et al. "Construction and function of fusion enzymes of the human cytochrome P450scc system," <i>DNA Cell Biol.</i> (1993) 12 :371	
	D14	HURT, E.C. et al. "The first twelve amino acids (less than half of the pre-sequence) of an imported mitochondrial protein can direct mouse cytosolic dihydrofolate reductase into the yeast mitochondrial matrix," <i>EMBO J.</i> (1985) 4 :2061-2068	
	D15	LI, J.M. AND G.C. SHORE "Reversal of the Orientation of an Integral Protein of the Mitochondrial Outer Membrane" <i>Science</i> (1992) 256 :1815-1817	
	D16	LUCIANO, P. et al. "Functional Reconstitution of the Import of the Yeast ADP/ATP carrier mediated by the TIM10 Complex" <i>EMBO J.</i> (2001) 20 :4099-4106	
	D17	MEISINGER, C. et al. "Protein Import Channel of the Outer Mitochondrial membrane: a Highly Stable Tom40-Tom22 Core Structure Differentially Interacts with Preproteins, Small Tom Proteins, and Import Receptors" <i>Mol. Cell. Biol.</i> (2001) 21 :2337-2348	
	D18	NEUPERT, W. "Protein import into mitochondria," <i>Annu. Rev. Biochem.</i> (1997) 66 :863-917	

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	D19	PERARA and LINGAPPA "A former amino terminal signal sequence engineered to an internal location directs translocation of both flanking protein domains," <i>J. Cell Biol.</i> (1985) 101 :2292-2301	
	D20	RAPOPORT, D. and W. NEUPERT "Biogenesis of Tom40, core component of the TOM complex of mitochondria," <i>J. Cell Biol.</i> (1999) 146 :321-331	
	D21	SCHATZ, G. and B. DOBBERSTEIN "Common principles of protein translocation across membranes," <i>Science</i> (1996) 271 :1519-1526	
	D22	SMUTZER "Cell-free transcription and translation," <i>The Scientist</i> (2001) 15 :22	
	D23	STOCCO, D.M. and B.J. CLARK "Regulation of the acute production of steroids in steroidogenic cells," <i>Endocr. Rev.</i> (1996) 17 :221-244	
	D24	TSUJISHITA, Y. and J.H. HURLEY "Structure and lipid transport mechanism of a StAR-related domain," <i>Nature Struct. Biol.</i> (2000) 7 :408-414	
	D25	WILKINSON "Cell-free and happy: In Vitro translation and transcription/translation systems," <i>The Scientist</i> (1999) 13 :15	

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